

IV. Remarks

A. Status of the Application

Claims 1-4, 7, 9, 11, 14-18, 24-26, and 29-39 were previously pending. No claims are added or canceled by the present paper. Reconsideration of the application is respectfully requested in light of the above amendments and the following remarks.

B. Rejections Under 35 U.S.C. §112, First Paragraph

Claims 1-4, 7, 9, 11, 14-18, 24-26, and 29-34 stand rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. In particular, the Office Action noted that the limitation reciting “the convex outer portion having a fifth radius of curvature substantially similar to or larger than the first radius of curvature,” was not found in the specification. This rejection is respectfully traversed, for the following reasons.

As pointed out in MPEP §2163.02:

The subject matter of the claim need not be described literally (i.e., using the same terms or *in haec verba*) in order for the disclosure to satisfy the description requirement.

For example, the written description requirement is met where the claimed subject matter is disclosed in the drawings rather than in the written specification. In this regard, MPEP §2163(II)(A)(3)(a) explains that:

Possession [of the invention] may be shown in many ways. For example, possession may be shown by describing an actual reduction to practice of the claimed invention. Possession may also be shown by a clear depiction of the invention in detailed drawings . . . which permit a person skilled in the art to clearly recognize that applicant had possession of the claimed invention. . . .

An applicant may show possession of an invention by disclosure of drawings or structural chemical formulas that are sufficiently detailed to show that applicant was in possession of the claimed invention as a whole. See, e.g., *Vas-Cath*, 935 F.2d at 1565, 19 USPQ2d at 1118 (“drawings alone may provide a ‘written description’ of an invention as required by Sec. 112\”); *In re Wolfensperger*, 302 F.2d 950, 133 USPQ 537 (CCPA 1962) (the drawings of applicant’s specification provided sufficient written descriptive support for the claim limitation at issue); . . .

Consequently, even though the detailed description specification of the present application does not contain the phrase “a fifth radius of curvature substantially similar to or larger than the first radius of curvature,” it is respectfully submitted that the present application does in fact include a proper written description of this subject matter, because the drawings of the present application disclose at least one embodiment that supports this particular claim language. In that regard, Applicants would at least point to Figs. 5 and 6—illustrating a “substantially similar” radius of curvature—and Figs. 7 and 8—illustrating a “larger” radius of curvature—as supporting the recited claim language. Fig. 5 is reproduced below in modified form to better illustrate the substantially similar radii of curvature. Fig. 7 is reproduced below in original form.

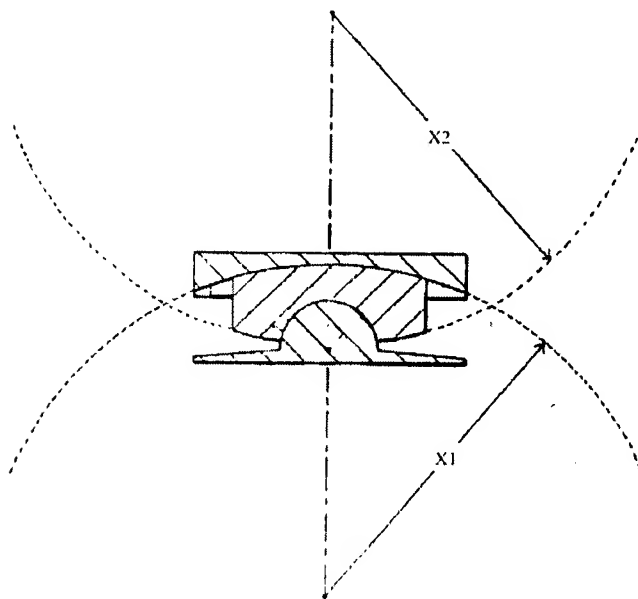


Fig. 5

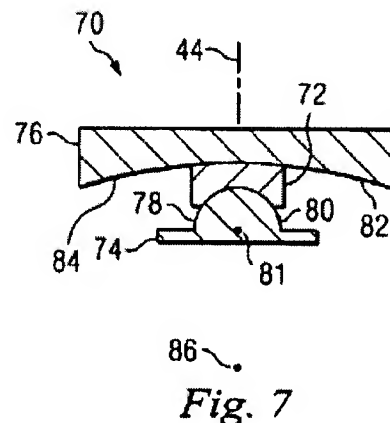


Fig. 7

In response to the Office Action’s point that the surface of Fig. 7 seems flat, Applicants would agree that the surface is substantially flat such that its radius of curvature approaches infinity, which is necessarily larger than the first radius of curvature. Thus, supporting the fifth radius of curvature being larger than the first radius of curvature. However, by the present paper Applicants have amended claim 1 to remove the limitation “or larger than the first radius of curvature” without prejudice to or disclaimer of the subject matter. Accordingly, Applicants request that the §112, first paragraph rejection of claims 1-4, 9, 11, 14-18, 24-26, and 29-34 be withdrawn.

C. Objection to the Specification

The specification stands objected to as failing to provide proper antecedent basis for the claimed subject matter. Applicants have amended the specification without adding any new matter to describe a “surface having a fifth radius of curvature substantially equal to the first radius of curvature.” In that regard, the new sentences added to paragraph [0040] find support at least in Figs. 2, 5, and 6 and/or paragraphs [0035] and [0040]. Accordingly, Applicants request that the objection to the specification be withdrawn.

D. Claim Rejections Under 35 U.S.C. §102

1. The Zdeblick Application

Claims 1-3, 7, 9, 14-18, 24, 25, 29, and 30 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent Application Publication No. 2002/0082701 to Zdeblick et al. (“the Zdeblick application”).

The PTO provides in MPEP § 2131 that

“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). ... “The identical invention must be shown in as complete detail as is contained in the ... claim.” *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).
(emphasis added)

Therefore, to sustain the rejection of claims 1-3, 7, 9, 14-18, 24, 25, 29, and 30 the Zdeblick application must disclose each and every element in as complete detail as recited in the claims.

With respect to amended independent claim 1, however, the Zdeblick application does not appear to disclose, “the center member being in articulating engagement with the first and second members and including: a convex third surface for movably mating with the concave recess defined by the first curve of the first surface ... a fourth surface having a concave central portion ... for movably mating with the convex projection defined by the second curve of the second surface,” as recited. In that regard, the shells 112, 114 of implant 110 constrain less than fifty percent of the height of spacer or insert 116 to allow “substantial movement in the spacer to

absorb compressive loads applied to the implant.” Paragraph [0077]. That is, the implant 110 functions by deformation or compression of the spacer 116. There does not appear to be any disclosure of the upper and lower shells 112, 114 articulating with respect to the spacer 116 as required by independent claim 1.

Further, Applicants still assert that the Zdeblick application does not appear to disclose, “the first member comprising a first surface with a first curve defining a concave recess, the first curve having a first radius of curvature; ... the second member comprising a second surface with a second curve defining a convex projection, the second curve having a second radius of curvature smaller than the first radius of curvature,” as recited. Instead, the concave recess and the convex projection—as indicated by the Examiner’s modification of Fig. 16 of the Zdeblick application as set forth in the previous Office Action—appear to have similar radii of curvature. If there is any difference between the radii, it appears that the convex projection may have a slightly larger radius of curvature than the concave recess, contrary to the requirements of independent claim 1.

Accordingly, for at least these reasons the Zdeblick application fails to teach all of the recited elements of independent claim 1. Claims 2, 3, 7, 9, 14-18, 24, 25, 29, and 30 depend from and further limit claim 1. Therefore, Applicants respectfully request that the §102(b) rejection of claims 1-3, 7, 9, 14-18, 24, 25, 29, and 30 over the Zdeblick application be withdrawn.

2. The Judet Patent

Claims 1-4, 7, 9, 11, 14-18, 24-26, 29, and 30 stand rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,314,485 to Judet (“the Judet patent”). Therefore, to sustain the rejection of claims 1-4, 7, 9, 11, 14-18, 24-26, 29, and 30 the Judet patent must disclose each and every element in as complete detail as recited in the claims.

However, claim 1 requires, “An intervertebral implant.” As indicated by the title—“Total Prosthesis of the Wrist”—the Judet patent is directed to “a total prosthesis of the wrist which comprises means for mechanically reproducing the kinematics of a healthy wrist.” Col. 1, ll. 6-8. There is simply no disclosure of the total wrist prosthesis being used as a vertebral implant. Further, one skilled in the art would not look to implant a wrist prosthesis into the spinal column due to the substantial differences in anatomy and associated kinematics and load

bearing between the wrist and the spinal column. Accordingly, the Judet patent necessarily fails to disclose the recited elements of independent claim 1. For at least this reason the Judet patent fails to teach all of the recited elements of independent claim 1. Claims 2-4, 7, 9, 11, 14-18, 24-26, 29, and 30 depend from and further limit claim 1. Therefore, Applicants respectfully request that the §102(b) rejection of claims 1-4, 7, 9, 11, 14-18, 24-26, 29, and 30 over the Judet patent be withdrawn.

3. The Sennwald Patent

Claims 1-4, 7, 9, 11, 14-18, 24-26, 29-34, and 39 stand rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,507,821 to Sennwald et al. (“the Sennwald patent”). Therefore, to sustain the rejection of claims 1-4, 7, 9, 11, 14-18, 24-26, 29-34, and 39 the Sennwald patent must disclose each and every element in as complete detail as recited in the claims.

However, similar to the Judet patent discussed above and as indicated by its title—“Artificial Wrist Joint”—the Sennwald patent is directed to an artificial wrist joint and not “An intervertebral implant” as required by claim 1, nor “An implant for positioning between a first vertebra and a second vertebra” as required by independent claim 39. First, the Sennwald patent makes no mention of using the disclosed artificial wrist joint as a vertebral implant. Further, one skilled in the art would not look to implant a artificial wrist joint into the spinal column due to the substantial differences in anatomy and associated kinematics and load bearing between the wrist and the spinal column. Accordingly, the Sennwald patent necessarily fails to disclose each and every element in as complete detail as recited in independent claims 1 and 39. Claims 2-4, 7, 9, 11, 14-18, 24-26, and 29-34 depend from and further limit claim 1. Therefore, Applicants respectfully request that the §102(b) rejection of claims 1-4, 7, 9, 11, 14-18, 24-26, 29-34, and 39 over the Sennwald patent be withdrawn.

4. The Casutt Application

Claims 1, 7, 9, 11, 14-18, 24-26, 29, and 30 stand rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent Application Publication No. 2003/0045939 to Casutt et al. (“the Casutt application”). Therefore, to sustain the rejection of claims 1, 7, 9, 11, 14-18, 24-26, 29,

and 30 the Casutt application must disclose each and every element in as complete detail as recited in the claims.

With respect to amended independent claim 1, however, the Casutt application does not appear to disclose, “the center member being in articulating engagement with the first and second members and including: a convex third surface for movably mating with the concave recess defined by the first curve of the first surface ... a fourth surface having a concave central portion ... for movably mating with the convex projection defined by the second curve of the second surface,” as recited. In that regard, the artificial intervertebral disc B includes “two end plates (1, 2) which bound a hollow space (4), which is filled with an **elastically and/or plastically deformable** nucleus (3), at two opposite sides, with the hollow space (4) being enclosed by a tubular fibre ring (5).” Abstract (emphasis added). That is, the artificial intervertebral disc B functions by deformation or compression of the nucleus (3) and the “fibre” ring (5). There is simply no disclosure of the end plates (1, 2) articulating with the nucleus (3) as required by independent claim 1. Accordingly, for at least this reason the Casutt application fails to teach all of the recited elements of independent claim 1. Claims 7, 9, 11, 14-18, 24-26, 29, and 30 depend from and further limit claim 1. Therefore, Applicants respectfully request that the §102(b) rejection of claims 1, 7, 9, 11, 14-18, 24-26, 29, and 30 over the Casutt application be withdrawn.

E. Claim Rejections Under 35 U.S.C. §103

Claims 31-39 stand rejected under 35 U.S.C. §103(a) as being unpatentable over the Casutt application. Applicants respectfully traverse the rejection of these claims on the grounds that the Casutt application is defective in establishing a *prima facie* case of obviousness.

In *KSR Int’l. Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1739 (2007), the Court stated that “a patent composed of several elements **is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.** Although common sense directs one to look with care at a patent application that claims as innovation the combination of two known devices according to their established functions, it can be important to identify a **reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does.** This is so because inventions in

moist, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.” *Id.* At 1741 (emphasis added).

As the PTO recognizes in MPEP § 2142:

... The examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness. If the examiner does not produce a *prima facie* case, the applicant is under no obligation to submit evidence of nonobviousness...

In the present application, a *prima facie* case of obviousness does not exist with respect to claims 31-39 for at least the reasons set forth below.

First, as shown above the Casutt application does not disclose or suggest all of the recited elements of independent claim 1. Claims 31-34 depend from and further limit claim 1. Accordingly, for at least the same reasons the Casutt application fails to disclose all of the recited elements of claims 31-34. Further, no reason—other than hindsight based on the present invention—has been provided for modifying the Casutt application to include the limitations recited in these dependent claims. In that regard and as noted above, *KSR* notes that it is important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does. Clearly, changing the structural profile of the artificial intervertebral disc of the Casutt application to include the recited limitations would change both the structure and the resulting kinematic properties of the disc. Further, the Casutt application notes that “[i]t is decisive for the function of the artificial intervertebral disc that the nucleus formed in this way preferably completely fills up the hollow space which the cover plates form with the fibre ring.” Paragraph [0010] Since the nucleus is filled as a fluid, its shape is defined by the cover plates and the fiber ring. Accordingly, **changing the shape of the nucleus requires changing the shape of every component of the device.** Such substantial structural changes to the disclosed disc cannot be considered “a mere change in the shape of the component” as suggested by the Office Action. Thus, a *prima facie* case of obviousness has not been established with respect to claims 31-34 and Applicants request that the §103 rejection of claims 31-34 over the Casutt application be withdrawn.

With respect to independent claim 35, the Casutt application at least fails to disclose or suggest “a center member positioned at least partially between the first member and the second

member and in articulating engagement with the first and second member,” as discussed above with respect to claim 1. Further, the Casutt application at least fails to disclose “wherein the first member, second member, and center member are formed of a relatively rigid biocompatible material.” In that regard, the nucleus (3) of the Casutt application is “elastically and/or plastically deformable.” Abstract. Further, one skilled in the art would not modify the nucleus to be a rigid material because “[t]he elastic behaviour of the artificial intervertebral disc of the invention is in this respect determined by the materials encompassing the fibre ring and the nucleus.” Paragraph [0009]. Accordingly, for at least these reasons a *prima facie* case of obviousness has not been established with respect to independent claim 35. Claims 36-38 depend from and further limit claim 35. Thus, Applicants request that the §103 rejection of claims 35-38 over the Casutt application be withdrawn.

Finally, independent claim 39 recites at least some limitations similar to those set forth in dependent claims 31-34. As discussed above, changing the shape of the nucleus as suggested by the Office Action, requires changing the shape of every component of the device. Such substantial structural changes to the disclosed disc cannot be considered “a mere change in the shape of the component” as suggested by the Office Action. Thus, a *prima facie* case of obviousness has not been established with respect to independent claim 39 either. Accordingly, Applicants request that the §103 rejection of claim 39 over the Casutt application be withdrawn.

V. Conclusion

It is believed that all matters set forth in the Office Action have been addressed and that all of the pending claims are in condition for allowance. Should the Examiner deem that any further amendment is necessary to place this application in condition for allowance, the Examiner is invited to contact the undersigned attorney at the telephone number noted below.

Respectfully submitted,



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